

Evaluating A Novel Follow-Up Intervention To Improve The Delivery
Of Follow-Up Care For Low-Risk Breast Cancer Survivors In Wisconsin

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**University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research**

Study Title: Evaluating A Novel Follow-Up Intervention To Improve The Delivery Of Follow-Up Care For Low-Risk Breast Cancer Survivors In Wisconsin

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Invitation and purpose of the study

We invite you to take part in a research study about breast cancer follow-up care. We are inviting you because you are a breast cancer survivor, diagnosed within the last 6-24 months.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research study is to develop a new approach to breast cancer follow-up care, titled REASSURE, that improves the quality of follow-up care and reduces unnecessary visits. We also want to learn about your overall experience with breast cancer follow-up. The study is being done at the University of Wisconsin. About 100 women from two UW Health Oncology clinics will participate.

What will happen in this study?

If you decide to participate in this research, you will be randomized (e.g., like flipping a coin) to one of two groups:

1. Usual follow-up care. If you are randomized to usual follow-up care, you will attend your follow-up visits as recommended by your oncology provider.
2. REASSURE follow-up. If you are randomized to the REASSURE follow-up group, follow-up will be determined by your responses to a survey sent before each follow-up visit. This survey was developed with input from oncologists and survivors to thoroughly assess how survivors are doing. If you report symptoms or concerns on the survey that reach a certain level, you will be recommended to attend your follow-up as scheduled. Your provider will have the opportunity to review your responses prior to the visit.

If you do not report symptoms or concerns, you will be recommended to drop the scheduled follow-up visit. You will have the option of keeping the visit if you prefer. You may also reach out to your provider at any time with concerns. In both cases, you will be sent an email message with information after the visit. Our goal is for you to have at least one in-person visit per year with your oncology provider.

Participants in both the usual follow-up care and the REASSURE follow-up groups will complete a number of surveys during the course of the study including:

A 5-10 minute baseline survey (after consent to participate)

A survey asking about symptoms or concerns you may have related to your breast cancer (approximately 4 weeks before a follow-up visit). This will be sent by email and will take 5-15 minutes to complete. This will be completed before each follow-up visit. We anticipate this will be completed 3-5 times during the study.

Survivors who report symptoms or concerns will be sent a brief survey after each follow-up visit. This will be sent online and will take less than 5 minutes to complete. We anticipate this could be completed 0-5 times during the study (depending on whether symptoms or concerns are reported on the pre-visit survey).

A final survey at the end of study (around 18 months after consent to participate).

Survivors randomized to the REASSURE group:

You may also have the option of participating in a 45-minute video or phone interview. Both the survey and interview will ask about your experience with this new REASSURE follow-up process. As part of the study, we will audio record and transcribe this interview. This will allow us to listen closely to you during the interview without needing to take as many notes. We will delete all recordings at the end of the study. Recordings will not be used for purposes outside of the study or in any papers or publications.

For all study participants, the research team will review your chart to obtain more information about you and the cancer.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you. To do this study, we will use the following types of PHI:

- Things you tell the researchers about your health

- Data about your health obtained from surveys

- Select medical record information such as your cancer diagnosis and treatment plan

- Contact information

How long will I be in this study?

Most participants will be in this study for about 20 months. Completing an interview may extend your participation by an additional 1-4 months. Your active participation in this study will end after completion of the final 18-month survey or interview (if you are selected for and elect to complete an interview).

How is being in this study different from my regular health care?

For survivors who are randomized to the usual care group, follow-up will be the same as your regular health care.

Survivors who are randomized to the REASSURE group may have fewer clinic visits with their providers. How many visits you have will be based on your responses to the questionnaire asking about your symptoms or concerns. If you report symptoms or concerns that reach a pre-established threshold, you will attend your follow-up visits as scheduled. If you do not report symptoms or concerns, you will be recommended to reschedule the visit for a future date. Our goal is for you to have at least one visit per year with your oncology provider.

Do I have to be in the study? What if I say “yes” now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. If you choose to participate, you may

still withdraw from the study at any time. If you decide not to take part in the study, the health care you receive will not be affected in any way. If you choose to leave the study, you will be scheduled to meet with your oncology provider as per the usual follow-up routine; the health care you receive will not be affected in any other way.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is complete. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time.
- If you take back your authorization, information that was already collected may still be used and shared with others for research purposes only, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research.
- To take back your authorization, please write to Dr. Heather Neuman at: K6/142 CSC, 600 Highland Ave, Madison, WI 53792-7375

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get care for your breast cancer. If you decide not to take part in the study or if you choose to leave the study, the health care you receive will not be affected in any way.

Will being in this study help me in any way?

Being in this study may reduce some burden of follow-up care by reducing the need for in-person visits and/or reassuring you of your low risk of recurrence. Your participation in the study may also benefit other people in the future by helping us learn more about symptoms and concerns of breast cancer survivors and this new approach to follow-up.

What are the risks?

Because this study involves changing standard follow-up care, there is the risk that a cancer recurrence or other condition will not be identified until your next visit. However, we think this risk is very small based on the type of breast cancer you had.

There is a risk that your information could become known to someone not involved in this study. The survey could cause stress and anxiety because the topics can be sensitive in nature.

Will being in this study cost me anything?

There will be no cost to you for participating in this study. Any follow-up visits recommended would be considered part of standard breast cancer follow-up and billed to your insurance company.

Will I be paid or receive anything for being in this study?

You will receive a \$10 incentive for completing the surveys for each follow-up visit (\$10 per visit, total \$30-\$50 over the study period) and an additional \$20 incentive for completing the 18-month outcome survey. If you are selected and participate in the end of study interview, you will receive an additional \$50.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

We cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

What will happen to my data after my participation ends?

We will keep your data for seven years. Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers. We will use the data in future research projects about breast cancer survivorship.

Who at UW-Madison can use my information?

Members of the research team

Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

U.S. Office for Human Research Protections

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record, but your medical record might say that you participated in this study. Additionally, a note may be placed in your medical record at the time of the questionnaire asking about symptoms and concerns indicating the plan for follow-up.

What if I have questions?

If you have questions about this research or you feel you have been harmed by participating in this study, please contact the study coordinator by email: reassure@surgery.wisc.edu. You may also contact the Lead Researcher, Dr. Heather Neuman, at (608) 262-2025. If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Use of Email for Research

We are requesting your email address so we can send you an electronic version of the survey. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Dr. Heather

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Lead Researcher: Dr. Heather Neuman, (608) 262-2025

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Neuman at (608) 262-2025 or the nurse triage line at 608-265-1700.

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Please check the following box that applies to you:

☐ Yes, you may use email to contact me for this study.

My preferred email address is: _____

☐ No, I do not want to be contacted by email. Please contact me by phone

My preferred phone number is: _____

Printed Name of Research Participant

Signature of Research Participant

Date

Signature of Person Obtaining Consent and Authorization

Date

****You will receive a copy of this form****